IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

(1) UNITED STATES OF AMERICA, *ex rel.* SANDRA WAGNER	)	
Plaintiffs,	)	
v.	)	**Case No. 15-CV-260-GKF-JFJ**
(1) CARE PLUS HOME HEALTH CARE, INC.,	)	
(2) PRASAD ITTY and	)	
(3) KUMAR GOVIND	)	
Defendants.	)	

UNITED STATES' STATEMENT OF INTEREST

The United States submits this Statement of Interest, pursuant to 28 U.S.C. § 517, to respond to certain arguments made in Defendants' Brief in Support of its Motion to Dismiss. Although the United States has not intervened in this action, it remains the real party in interest. *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 930 (2009). The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, is the United States' primary tool to redress fraud on the government. Thus, the United States has a keen interest in the development and correct application of the law in this area. The United States submits this brief to respond to Defendants' argument that the existence of physician certifications insulates Defendants from FCA liability for billing the government for home health services for patients who were not homebound. The Court should reject these arguments for the reasons discussed below. The United States otherwise takes no position on the motion.

Physician certifications do not immunize home health providers from FCA liability.

Defendants contend that physician certifications that a patient is homebound and entitled to home health services immunize Defendants from False Claims Act liability as to claims for

patients alleged to be non-homebound.[1] However, Defendants' contention misconstrues the role of physician certifications in Medicare's home health benefit, as well as the obligations that the False Claims Act imposes on all who seek payment from the government. Under the statutory and regulatory framework underpinning this benefit, and under the False Claims Act, a home health care provider has an independent obligation to ensure that it only submits claims to Medicare for billable services. This includes the obligation not to bill for patients who are not homebound.

Part 424 of Title 42 of the Code of Federal Regulations, titled "Conditions for Medicare Payment" states that "Medicare Part A or Part B pays for home health services only if a physician certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate." 42 C.F.R. § 424.22. But the physician certification alone is not enough. Medicare also conditions payment on the beneficiary actually being homebound and needing skilled services. 42 C.F.R. § 409.41(c) conditions payment on all requirements contained in §§ 409.42-409.47 being met. Those requirements include the requirement that the patient is confined to the home. *See* 42 C.F.R. § 409.42(a). *See also United States ex rel. White v. Gentiva Health Servs., Inc.*, 2014 U.S. Dist. LEXIS 86156, at *45 (E.D. Tenn. June 15, 2014) (Doc. 57-1 at 78-91) ("Medicare conditions payment on the beneficiary actually being homebound and actually needing skilled services"). To that end, as Defendant acknowledges, home health agencies have the duty to "*verify* the patient's eligibility for the Medicare home health benefit *including homebound status*, both at the time of the initial assessment visit and at the time of the comprehensive assessment." 42 C.F.R. §484.55 (emphasis added). *See* Defendants' Brief at 7 (emphasis added).

[1] Defendants' Brief at 11 ("Whether a patient is eligible for Medicare home-health benefits is a determination made – and certified to – by the patient's physician."); ("Given their role in this process, physicians are often referred to as the "gatekeepers" for Medicare home-health benefits."); Defendants' Reply Brief at 4 ("[U]nder Medicare, a patient's eligibility for home health services is determined (and certified to) by the patient's physician and, thus, it's immaterial what an HHA administrator thinks about the patient's eligibility.").

This assessment occurs prior to the physician's eligibility certification and is a critical step in the eligibility determination process. *See United States ex rel. Prather v. Brookdale Senior Living Communities, Inc,* 838 F.3d 750 (6th Cir. 2016).

In the *Galatis* case, cited by Defendant to highlight the importance of the physician's certification, the Court noted that the certification is the "second document" submitted to the Department of Health and Human Services. *United States v. Galatis,* 849 F.3d 455, 457. "The first is a checklist known as an OASIS [Outcome and Assessment Information Set] Form, a 'voluminous document' that 'details the beneficiary's condition", and is completed by the home health medical staff, in response to the physician's referral. *Id* at 457. As noted by the Court in Galatis's co-defendant's case, Janice Troisi ("Troisi"), a nurse acting as Clinical Director for the home health agency, "professed her 'expertise' in 'PPS', the process by which medical providers submit payment requests to Medicare based on patients' OASIS forms." *United States v. Troisi,* 849 F.3d 490, 495. Troisi was convicted of one count of conspiracy to commit health care fraud and 11 counts of substantive health care fraud, based on her role in assisting the home health agency bill for services provided to patients who were ineligible, either because they were not homebound or required no skilled nursing services. The *Troisi* Court recognized the coordination required of all health care providers in the home health patient eligibility determination.

So, while physicians have been referred to as "gatekeepers" of Medicare's home health benefits, as in *United States v. Patel,* 778 F.3d 607, 616 (7th Cir. 2015), the cases cited by Defendants support the United States' position that the the regulations clearly require both an assessment by the home health staff and a Form 485, signed by the authorizing physician. The home health agency's obligation is independent of the physician certification requirement and requires Defendants to bill only for patients who are actually homebound. Home health agencies

are in a position to assess medical needs and the homebound status of patients during their regular home health visits. Thus, if a clinician notes that a patient was not confined to the home (*e.g.*, routinely driving self over 40 miles to wound care clinic, as alleged in Complaint ¶ 121), it is the home health agency's responsibility, regardless of the physician's initial certification, to ensure that it only bills for eligible patients and not simply to continue to bill for a patient who is ineligible for the Medicare home health benefit. The physician certification plainly serves a different function. It is a forward-looking projection of medical need at the time the beneficiary's plan of care is established – the start of the sixty-day episode of care – and an assessment of the beneficiary's homebound status at that time.[2] It is not a backward looking attestation that the beneficiary was homebound throughout a prior sixty-day episode of care or a promise that the patient will remain homebound going forward. The physician certification cannot, for example, take into account potential changes in the beneficiary's health throughout the episode of care that may have an impact on homebound status. In addition, it is based on an initial evaluation, not the regular and ongoing contact with the patient that home health agencies have through their home health visits, which may, and often do, provide the home health agency with insight contrary to that forming the basis for the physician's initial assessment. Very simply, the regulations for Medicare home health eligibility impose a system of checks and balances designed to protect the federal health benefit program. Responsibility for accurately assessing a beneficiary's homebound status rests with both the certifying physician and the home health agency submitting the claim for reimbursement.

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[2] "The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan." 42 C.F.R. § 424.22(a)(2). While the "as soon thereafter as possible" language in the regulations provides some leeway to providers in obtaining the certifying physician's signature, the timing requirements quite clearly demonstrate that the certifying physician's certification of medical need is designed to be a judgment at the outset of the episode of care rather than a post-hoc analysis of the services actually provided by the home health agency throughout the course of a sixty-day episode.

Likewise, the False Claims Act holds liable "any person who . . . knowingly presents . . . false claims to the United States," 31 U.S.C. § 3729(a)(1), regardless of whether others may also have a role in the claims submission process. At the appropriate time, Defendants may decide to present to the jury the physician certifications here as evidence that it believed the patients were homebound and the services for which it billed were eligible to be paid. Those physician certifications would be one piece of evidence, however, not an automatic defense to FCA liability at the motion to dismiss stage. Relator can thus allege that Defendants submitted false claims with the requisite *scienter*, and can do so without alleging that any physician certification was deficient or tainted in any way.

The Court should reject Defendants' argument, however, that a physician's certification that a patient is homebound constitutes a subjective clinical decision that therefore cannot give rise to FCA liability. This argument is contrary to the FCA and precedent. As a general rule, claims for payment are "false" within the meaning of the statute if the party submitting them is not entitled to be paid because a condition of payment has not been met. *See United States ex rel. Augustine v. Century Health Servs.*, 289 F.3d 409, 415 (6th Cir. 2002); *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) ("[C]laims for medically unnecessary treatment are actionable under the FCA"). As set forth above, Medicare conditions payment on patients actually being homebound – and not just a physician certification affirming homebound status – so claims for patients who are not homebound are "false" under the FCA. Factfinders are well-equipped to weigh evidence of whether patients are homebound and to evaluate clinical information and other documentation in a medical record, relevant policies and guidance promulgated by the government or other entities, and expert and other witness testimony. A jury may need to weigh conflicting medical evidence, but that happens in many cases. *See, e.g., United*

States v. Persaud, No. 16-3105. 2017 WL 2557823, at *7 (6th Cir. June 13, 2017) (motion to publish granted July 7, 2017) (holding that jury permissibly credited the testimony of government experts to find a physician had knowingly required his patients to undergo unnecessary cardiac tests and procedures); *United States v. Patel,* 485 F. App'x 702, 709 (5th Cir. 2012) (unpublished) (holding that a jury "was permitted to credit" the testimony of government experts regarding the lack of medical necessity and the existence of false statements over contrary testimony and evidence from the defendant); *Weese v. Schukman,* 98 F.3d 542, 547-48 (10th Cir. 1996) (reinstating jury verdict in medical malpractice case because it was "within the jury's role as the factfinder to decide that [the plaintiff's] witnesses were not credible and therefore reject their testimony").

While Defendants might not be liable if they reasonably, but erroneously, believed a patient was homebound, that would be only because Defendants did not act "knowingly," *see* 31 U.S.C. §3729(a)(1)(A), (B) – not because Defendants' claim was reimbursable (*i.e.,* not "false"). The FCA imposes liability for the "knowing[" presentment of a false claim, which includes "actual knowledge,", "deliberate ignorance," or "reckless disregard." 31 U.S.C. §3729(a), (b)(1). If Defendants submitted a claim in good faith, the knowledge requirement would not be met and Defendants would not be liable, even if the claim was not reimbursable because the patient was not actually homebound. But that would not mean the claim was not false; as the Supreme Court recently explained, courts should address "concerns about fair notice and open-ended liability . . . through strict enforcement of the Act's materiality and scienter requirements," not by "adopting a circumscribed view of what it means for a claim to be false or fraudulent." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016) (quotation marks omitted); *see also United States ex rel. Oliver v. Parsons Co.,* 195 F.3d 457, 460 (9th Cir. 1999)

("A contractor relying on a good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or 'reasonable' but because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met."). Nowhere does the FCA distinguish between "objective" and "subjective" false claims when it prohibits false claims submission. The potential for a reasonable but erroneous belief that a claim was eligible for payment goes not to falsity but to *scienter*: to "whether the defendant actually knew or should have known that its conduct violated a regulation." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017).

CONCLUSION

For the foregoing reasons, the United States respectfully asks the Court to reject Defendants' arguments addressed in this Statement of Interest. The United States takes no position on other arguments made. The United States also asks that, if the Court dismisses the relator's Complaint because it is inadequately plead, it make such dismissal without prejudice to the United States. *United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 456 (5th Cir. 2005) (concluding "dismissal with prejudice as to the United States [is] unwarranted where . . . the relator's claims were dismissed on a Rule 12(b)(6) motion based on lack of specificity in the complaint as required by Rule 9(b)").

Dated: September 27, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2017, using the ECF System, I electronically transmitted the foregoing to the Clerk of Court for filing and transmittal of a Notice of Electronic Filing to the following ECF registrants:

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